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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/079,130	02/20/2002	Richard B. Meagher	21099.0074U2	6995

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EXAMINER

OUSPENSKI, ILIA I

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 11/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/079,130

Applicant(s)

MEAGHER ET AL.

Examiner

ILIA OUSPENSKI

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 17, 19-22, 27-116 and 120-150 is/are pending in the application.
- 4a) Of the above claim(s) 35-41, 43-111, 122-129 and 139-147 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 17, 19-22, 27-34, 42, 112-116, 120-121, 130-138 and 148-150 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's amendment/remarks, filed 09/09/2005, are acknowledged.

Claims 5 – 16 and 117 – 119 have been cancelled.

Claims 18 and 23 – 26 have been cancelled previously.

Claims 1 – 4, 17, 34, 42, 114 – 116, and 130 – 136 have been amended.

Claims 148 – 150 have been added.

Claims 1 – 4, 17, 19 – 22, 27 – 116, 120 – 150 are pending.

Claims 35 – 41, 43 – 111, 122 – 129, and 139 – 147 have been withdrawn from consideration by the Examiner as being drawn to nonelected inventions.

Claims 1 – 4, 17, 19 – 22, 27 – 34, 42, 112 – 116, 120 – 121, 130 – 138, and 148 – 150 are under consideration in the instant application.

2. This Office Action will be in response to applicant's arguments, filed 09/09/2005.

The rejections of record can be found in the previous Office Action, mailed 03/04/2005.

The text of those sections of Title 35 USC not included in this Action can be found in a prior Office Action.

3. The objections and rejections of record have been withdrawn in view of Applicant's amendment and arguments, except as set forth herein.

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4. Claims 1 – 4, 17, 19 – 22, 28 – 33, 42, 112 – 116, 120 – 121, and 130 – 138 stand rejected, and newly added claims 148 – 150 are rejected, under **35 U.S.C. 103(a)** as being unpatentable over Matsuuchi et al. (of record, reference A57 on the IDS, see entire document) in view of Maciak et al. (of record, reference A3 in the IDS, see entire document), as evidenced by the instant specification on page 2, last paragraph.

Applicant's arguments have been fully considered but have not been found convincing.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Further, Applicant argues that the molecular and cellular mechanisms taught by the references differ from those disclosed in the instant application. In response, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). See MPEP 2112.

Applicant argues that Maciak et al. did not know how the observed higher than average density of immunoglobulin appears on the cell surface, nor did Maciak et al. know for certain that the immunoglobulin being detected on the hybridoma cell surface was the membrane form of immunoglobulin.

This is not found persuasive, because the discovery of a previously unknown molecular mechanism of immunoglobulin targeting to the cell surface, which Maciak et

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al. did not appreciate, does not disqualify the hybridoma cells taught by Maciak et al. as prior art. See MPEP 2112. Furthermore, the teachings of Maciak et al. regarding the importance of obtaining maximal yields of antibodies from hybridoma cultures, and that the yield is positively correlated with the surface expression of the antibody, provide motivation for applying the teachings of Matsuuchi et al. to hybridoma cells, regardless of the underlying mechanisms.

Applicant further argues that there is no indication in Matsuuchi et al. that the results obtained by transfecting a nucleic acid encoding Ig α , Ig β , and the membrane form of antibody heavy chain into pituitary cells would result in an increase in the amount of antibody bound to the surface of any other cell type, such as hybridoma cell.

This is not found persuasive, because Matsuuchi et al. teach that MB-1/Ig α and Ig β are sufficient for cell surface expression even in the absence of other B-cell-specific components (page 3404, first column, last paragraph). This provides a clear expectation of success for a skilled artisan in applying these teachings to other cell types, and in view of motivation provided by Maciak et al., to hybridoma cells in particular.

Applicant further argues that the teachings Matsuuchi et al. pertain to a recombinant form of antibody heavy chain, and do not teach or suggest using an endogenous membrane form of monoclonal antibody.

This is not found persuasive, because the newly added limitation of "endogenous" refers to a process of producing the antibody and not to the structure or property of the final product. Inasmuch as the structure of the antibody produced from an endogenous gene or from a recombinant construct is the same, the limitation does not distinguish the claimed invention from the prior art. See e.g. *Ex parte Gray*, 10 USPQ2d 1922 (Bd. Pat. App. & Inter. 1989).

Applicant further presents a reference (Sakaguchi et al., EMBO J., 1988, 7: 3457 – 3464) showing that MB-1/Ig α is expressed in cells of B lymphocyte lineage, and argues that since hybridoma cells allegedly downregulate Ig α expression, one of skill in the art could not expect that hybridoma cells would express Ig α when transfected with a vector encoding Ig α .

This is not found persuasive, because Matsuuchi et al. teach that Ig α can be successfully expressed in transfected cells that do not normally express Ig α .

Applicant further presents a reference (Milcarek et al., Molec. Immunol., 1996, 33: 691 – 701) showing that upon fusion of myeloma cells with a B cell line, production of the secretory form of Ig heavy chain mRNA predominated over that of the membrane encoding form by 100:1, and argues that given these results, one of skill in the art could not expect that the endogenous membrane form of the immunoglobulin would be produced to any appreciable extent.

This is not found sufficiently persuasive, because first, as the skilled artisan was aware, the mRNA levels do not necessarily correlate with the levels of the respective proteins, and second, the reference compares the levels of membrane and secretory forms of Ig heavy chain to each other, whereas both the prior art reference of Matsuuchi et al. and the instant claims compare the level of the membrane-bound antibody in cells expressing Ig α to the level of the membrane-bound antibody in cells which do not express Ig α , i.e. Applicant's argument is not seen as sufficient to showing the alleged distinction between the prior art teachings and the instantly claimed invention.

Therefore, the rejection of record is maintained for the reasons of record, as it applies to the amended and newly added claims. The rejection of record is incorporated by reference herein, as if reiterated in full.

5. Claim 34 stands rejected under **35 U.S.C. 103(a)** as being unpatentable over Matsuuchi et al. (of record, reference A57 on the IDS, see entire document) in view of Maciak et al. (of record, reference A3 in the IDS, see entire document), and further in view of Gossen et al. (US Patent 5,464,758; see entire document).

Applicant's arguments have been fully considered but have not been found convincing.

Applicant argues that one of skill in the art would not have combined the teachings of Matsuuchi et al. with the teachings of Maciak et al. to arrive at the claimed invention, and therefore, it would not have been obvious to combine the teachings of Matsuuchi et al. with the teachings of Maciak et al. with the teachings of Gossen et al., directed to the use of inducible promoters to arrive at the claimed invention.

Applicant's argument with regard to the combination of references of Matsuuchi et al. and Maciak et al. has not been found persuasive, as detailed supra.

Therefore, the rejection of record is maintained for the reasons of record. The rejection of record is incorporated by reference herein, as if reiterated in full.

6. Conclusion: no claim is allowed.

7. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILIA OUSPENSKI whose telephone number is 571-272-2920. The examiner can normally be reached on Monday-Friday 9 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ILIA OUSPENSKI
Patent Examiner
Art Unit 1644

November 4, 2005

PHILLIP GAMBEL
PHILLIP GAMBEL, PH.D
PRIMARY EXAMINER
TECH COUNCIL 1600
11/7/05